



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 12/11/96

SUBJECT: PP# 7E3489 REQUEST FOR EXTENSION OF TIME-LIMITED
TOLERANCES FOR BENOXACOR (CGA-154281) USED AS A
SAFENER.

DP Barcode: D231196 Caswell: 298C & 188CC
Class: Inert (Safener) CAS: 98730-04-1
PRAT Case#: 240741 40 CFR: §180.460

TO: Kerry Leifer, PM Team 45
ERMUS/RSB/RD (7505W)

FROM: William D. Cutchin, SanYvette Williams-Foy
Pilot Interdisciplinary Risk Assessment Team
RCAB/HED (7509C)

THRU: Michael S. Metzger, Acting Chief
RCAB/HED (7509C)

INTRODUCTION

Ciba-Geigy is proposing a two year extension of time-limited tolerances for the safener benoxacor. Tolerances are established for the residues of benoxacor, 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine, at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on the raw agricultural commodities for which a tolerance has been established for metolachlor. The time-limited tolerances were established to allow the registrant time to perform chronic oncology studies.

RECOMMENDATION

Aggregate risk estimates do not exceed HED's level of concern. This extension of time-limited tolerances should not pose an unacceptable dietary risk to infants and children. Therefore, HED has no objection to the issuance of a one year extension of

BENOXACOR

time-limited tolerances at 0.01 ppm for the residues of the safener benoxacor in/on the raw agricultural commodities for which a tolerance has been established for metolachlor.

Note: PIRAT is recommending only for a one year extension of the tolerances because the Cancer Peer Review Committee has not yet classified benoxacor as to its carcinogenicity. It is scheduled for review and classification in the near future (February 1997).

CONCLUSIONS

Hazard Assessment

1. Non-Dietary Exposure Endpoint Selection

- a) Short- and Intermediate-Term Risk. For short- and intermediate-term MOE calculations, the Ad Hoc TES Committee (PIRAT toxicologist, TBII Section head, SAB Chief) determined that worker exposure risks do not have to be calculated for benoxacor based on available data which indicated minimal dermal or inhalation toxicity (NOEL's for each greater than the limit dose).
- b) Chronic Risk. The Ad Hoc TES Committee did not recommend a NOEL for use in a chronic risk assessment, since a chronic exposure scenario does not exist for uses in benoxacor.
- c) Cancer Risk. Benoxacor has been referred to HED's Carcinogenicity Peer Review Committee (CPRC) and is scheduled (February 1997) for review and classification as to its carcinogenicity.

2. Dietary Endpoint Selection

- a) Acute Risk. For acute dietary risk assessment, the Ad Hoc TES Committee (same as above) determined that this risk assessment was not required because there were no data that might trigger an acute dietary risk.
- b) Chronic Risk. RfD = 0.004 mg/kg/day. A provisional RfD was established at an Ad Hoc RfD Committee meeting (12/10/96) based on a combined chronic toxicity/ oncogenicity study [MRID#: 42888704] in rats. The NOEL was 0.4 mg/kg/day. An uncertainty factor of 100 was used to calculate the RfD. The LEL of 2.0 mg/kg/day was based on increased non-neoplastic lesions of the stomach (including epithelial hyperplasia) and liver (including centrilobular enlargement and hepatocyte vacuolation in males). The Ad Hoc Committee members (PIRAT Toxicologist, TBI Branch Chief, TBII

Branch Chief, Reproductive Toxicologist, TBII Toxicologist) stated that, "the meaning of the biological significance of effects, other than in the stomach and liver, are questionable and contingent upon later review by HED's RfD Committee."

c) Cancer Risk. Benoxacor has been referred to HED's Carcinogenicity Peer Review Committee (CPRC) and is scheduled (February 1997) for review and classification as to its carcinogenicity.

d) Infants and Children

i) Developmental Toxicity Studies

Rat - In the developmental toxicity study (MRID#: 400288-15) in rats, the maternal (systemic) NOEL was 100 mg/kg/day. The maternal LOEL of 400 mg/kg/day was based on clinical observations, decreased body weight gain and decreased food consumption. The developmental (pup) NOEL was also 100 mg/kg/day. The developmental LOEL of 400 mg/kg/day was based on decreases in fetal weight, number of live fetuses, and uterine weight, increased early resorption, visceral malformations, and skeletal variations which were indicative of delayed development.

Rabbit - In the developmental toxicity study (MRID #400288-16) in rabbits, the maternal and developmental NOELs were both 12.5 mg/kg/day. The maternal and developmental LOEL of 62.5 mg/kg/day was based on decreased food consumption (maternal) and on the increased frequency of vertebral anomaly with or without an associated rib anomaly (developmental).

ii) Reproductive Toxicity Study

Rat - In the 2-generation reproductive toxicity study (MRID# 428887-03) in rats, the parental (systemic) NOEL was 3.55 mg/kg/day in males and 4.51 mg/kg/day in females. The parental LOEL of 34.84 mg/kg/day in males and 41.21 mg/kg/day in females was based on decreased body weight and body weight gain in both sexes and in both generations. The reproductive NOEL was 4.57 mg/kg/day. The reproductive LOEL's of 64.02 (F1) and 72.25 (F2) mg/kg/day were based on decreased pup body weight on lactation day (LD) 21.

Occupational Exposure

Because this action only involves extension of tolerances (the registrations are still current or have been extended), an occupational exposure assessment has not been conducted.

Aggregate Exposure

Dietary Exposure

1. The nature of the residue in plants and animals is adequately understood. The residue of concern is the parent compound as specified in 40 CFR 180.460.
2. Adequate enforcement methodology (GC/NPD) is available in PP#7E3489, MRID# 412108-02, 9/5/89, to enforce the tolerance expression.
3. Residues of benoxacor are not expected to exceed 0.01 ppm in the raw agricultural commodities for which a tolerance has been established for metolachlor (DP Barcode: D176695, CBTS#: 9683, F. Griffith, 4/23/92). The existing time-limited tolerances should be extended at these levels.
4. There is no reasonable expectation of finite secondary residues of benoxacor in animals, therefore meat, milk, poultry, and egg tolerances are not required (PP#7E3489, DEB#: 4660, MRID#: 408698-00 thru 09, F. Griffith, 4/3/89). No time-limited tolerances for the residues of benoxacor in animals commodities are required.
5. Benoxacor has been found to be stable while frozen (-18°C) for up to 28 weeks on corn and soy bean commodities (PP#7E3489, MRID#: 407321-07, DEB#: 4074, F. Griffith, 9/28/88). This is adequate to support the magnitude of residue data for benoxacor.
6. Residues of benoxacor have not been detected (<0.005 ppm) on corn, soybeans, and potatoes when applied at 5x the label rate (PP#7E3489, DEB#: 4660, MRID#: 408698-03, F. Griffith, 4/3/89). PIRAT considers it unlikely that any benoxacor residues would be found on crops rotated from crops treated at the recommended label rate.
7. No Codex Maximum Residue Limits (MRL) for benoxacor exist. Therefore, there are no issues of compatibility with respect to Codex MRLs and U.S. tolerances.
8. Acute Dietary Risk. This risk assessment is not required because the Ad Hoc TES Committee did not identify an acute dietary risk.

9. Chronic Dietary Risk. The existing benoxacor time-limited tolerances result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percents of the RfD:

U.S Population (48 States)	5%
Nursing Infants	5%
Non-Nursing Infants (<1 year old)	20%
Children (1-6 years old)	12%
Children (7-12 years old)	8%
Hispanics	6%
Non-Hispanic Others	5%
Males (13-19 years old)	5%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

10. Cancer Risk. Since the RfD Committee has yet to review and classify benoxacor as to its carcinogenic potential (schedules February 1997), a quantitative dietary cancer risk assessment was not conducted.

Exposure to Water

Environmental Fate Effects Division ground water data base has no information on benoxacor. In the absence of data, PIRAT must assume that benoxacor is persistent and mobile. There is no established Maximum Concentration Level for residues of benoxacor in drinking water. No Health Advisory Levels for benoxacor in drinking water have been established.

PIRAT does not have available data to perform a quantitative drinking water risk assessment for benoxacor at this time. Previous experience with persistent and mobile pesticides for which there have been available data to perform quantitative risk assessments have demonstrated that drinking water exposure is typically a small percentage of the total exposure when compared to the total dietary exposure. This observation holds even for pesticides detected in wells and drinking water at levels nearing or exceeding established MCLs. Based on this experience and our best scientific judgement, HED concludes that it is not likely that the potential exposure from residues in drinking water added to the current dietary exposure will result in an exposure which would exceed 100% of the RfD.

Non-occupational Exposure

Benoxacor is not registered for residential use. All metolachlor products to which benoxacor is added as a safener are commercial agricultural products not registered for residential use (personal communication, K. Liefer, RD, 12/9/96).

Cumulative Effects

At this time the Agency has insufficient information to make a determination that benoxacor and other substances that may have a common mode of toxicity would have cumulative effects. For the purposes of these time-limited tolerances, PIRAT has considered only effects from benoxacor.

Determination of Safety for Infants and Children

Based on current toxicological data requirements, the data base for benoxacor relative to pre- and post-natal toxicity is complete.

In the case of the developmental toxicity studies, the developmental and maternal NOEL's for both rats and rabbits occur at the same dose level for each species (100 mg/kg/day for rats 62.5 mg/kg/day for rabbits) and suggests that there is no special pre-natal sensitivity.

In the case of the 2-generation reproductive toxicity study, the reproductive NOEL of 4.57 mg/kg/day is higher than the parental NOEL's of 3.55 and 4.51 mg/kg/day for males and females, respectively. The LOEL's for parental and reproductive toxicity were both based on decreases in body weight. This suggests that there is no extra-sensitivity for infants and children. In addition, the reproductive NOEL of 4.57 is greater than 1100 times the RfD of .004 mg/kg/day which is the basis of the RfD.

SUPPLEMENTAL INFORMATION

Dietary Exposure

Table 1. Residue Consideration Summary Table	
PARAMETER	RESIDUE DATA
CHEMICAL	CGA-154281 (Benoxacor)
FORMULATION	CGA-154281
CROP	corn, soya, and potatoes
TYPE APPLICATION	ground
# APPLICATIONS	1
TIMING	with DUAL®
RATE/APPLICATION	0.125 lb ai/A (DUAL:Benoxacor, 1:30)
RATE/YEAR or SEASON	0.125 lb ai/A/season (DUAL:Benoxacor, 1:30)
MAXIMUM RESIDUE	<0.005 ppm (LOD)
RESTRICTIONS	Use with metolachlor only on crops with existing metolachlor tolerances.
RESIDUE DATA SOURCE	PP#7E3489, MRID# 4086989-03, 4/3/89
PERFORMING LAB	Ciba-Geigy

Attachments: DRES Analysis (12/10/96), IRLS Sheet

cc with Attachments: Cutchin, PIRAT, DRES (B. Steinwand), RCAB (D. McCall)

cc without Attachments: Williams-Foy, OREB (Chem File), Caswell File, TOX II Files (D. Liem & S. Makris), CBTS (PP#7E3489)

RDI: PIRAT: 12/11/96

CHEMICAL INFORMATION FOR CASWELL NUMBER 123BX

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Benoxycor Caswell #123BX CAS No. 98730-04-2 A.I. CODE: CFR No. 180.460	90d feeding- dog NOEL= 5.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:	90-Day rat study - NOEL=5 mg/kg-day. NOELs taken form FR notice.	UF -->1000 OPP RfD= 0.004000 EPA RfD= 0.000000	AD HOC RfD/PR COMMITTEE 12/10/96	PROVISIONAL RfD 12/10/96

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
03001AA	ALMONDS	3F2958			0.010000
03002AA	BRAZIL NUTS	3F2958			0.010000
03003AA	CASHEWS	3F2958			0.010000
03004AA	CHESTNUTS	3F2958			0.010000
03005AA	FILBERTS, HAZELNUTS	3F2958			0.010000
03006AA	HICKORY NUTS	3F2958			0.010000
03007AA	MACADAMIA NUTS (BUSH NUTS)	3F2958			0.010000
03008AA	PECANS	3F2958			0.010000
03009AA	WALNUTS	3F2958			0.010000
03010AA	BUTTER NUTS	3F2958			0.010000
03013AA	BEECHNUTS	3F2958			0.010000
05001AA	APRICOTS-FRESH	3F2957			0.010000
05001DA	APRICOTS-DRIED	3F2957			0.010000
05002AA	CHERRIES-FRESH	3F2957			0.010000
05002DA	CHERRIES-DRIED	3F2957			0.010000
05002JA	CHERRIES-JUICE	3F2957			0.010000
05003AA	NECTARINES	3F2957			0.010000
05004AA	PEACHES-FRESH	3F2957			0.010000
05004DA	PEACHES-DRIED	3F2957			0.010000
05005AA	PLUMS(DAMSONS)-FRESH	3F2957			0.010000
05005DA	PLUMS-PRUNES(DRIED)	3F2957			0.010000
05005JA	PLUMS, PRUNE-JUICE	3F2957			0.010000
08015AA	DILL	1F2495			0.010000
08048DA	PAPRIKA	5E3236			0.010000
11003AA	PEPPERS, SWEET, GARDEN	8E3616			0.010000
11003AB	CHILI PEPPERS	5E3236			0.010000
11003AD	PEPPERS-OTHER	9E3708			0.010000
13002AA	CELERY	0E3882			0.010000
13007AA	CABBAGE-GREEN AND RED	8E3637			0.010000
13010AA	CABBAGE-CHINESE/CELERY, INC. BOK CHOY	8E3637			0.010000
13016AA	FENNEL	0E3882			0.010000
13024AA	SPINACH TLT 11/15/98	SECT18			0.010000
14007AA	GARLIC	4E4286			0.010000
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	4E4286			0.010000
14011DA	ONIONS-DEHYDRATED OR DRIED	4E4286			0.010000
14013AA	POTATOES(WHITE)-WHOLE	9F2203			0.010000
14013AB	POTATOES(WHITE)-UNSPECIFIED	9F2203			0.010000
14013AC	POTATOES(WHITE)-PEELED	9F2203			0.010000
14013DA	POTATOES(WHITE)-DRY	9F2203			0.010000
14013HA	POTATOES(WHITE)-PEEL ONLY	9F2203			0.010000

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FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
14017AA	SHALLOTS	4E4286			0.010000
15001AA	BEANS-DRY-GREAT NORTHERN	1F2495			0.010000
15001AB	BEANS-DRY-KIDNEY	1F2495			0.010000
15001AC	BEANS-DRY-LIMA	1F2495			0.010000
15001AD	BEANS-DRY-NAVY (PEA)	1F2495			0.010000
15001AE	BEANS-DRY-OTHER	1F2495			0.010000
15001AF	BEANS-DRY-PINTO	1F2495			0.010000
15002AA	BEANS-SUCCULENT-LIMA	1F2495			0.010000
15003AA	BEANS-SUCCULENT-GREEN	1F2495			0.010000
15003AB	BEANS-SUCCULENT-OTHER	1F2495			0.010000
15003AC	BEANS-SUCCULENT-YELLOW, WAX	1F2495			0.010000
15004AA	CORN, POP	1F2521			0.010000
15005AA	CORN, SWEET	8F2081			0.010000
15006AA	PEANUTS-WHOLE	2F2720			0.010000
15007AA	PEAS(GARDEN)-MATURE SEEDS, DRY	1F2495			0.010000
15009AA	PEAS(GARDEN)-GREEN IMMATURE	1F2495			0.010000
15011AA	LENTILES-WHOLE	1F2495			0.010000
15011AB	LENTILES-SPLIT	1F2495			0.010000
15013AA	MUNG BEANS (SPROUTS)	1F2495			0.010000
15015AA	OKRA	1F2495			0.010000
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	1F2495			0.010000
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	1F2495			0.010000
15023AA	BEANS-DRY-PIGEON BEANS	1F2495			0.010000
15027AA	BEANS-UNSPECIFIED	1F2495			0.010000
15029AA	SOYBEANS-SPROUTED SEEDS	2F2720			0.010000
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	1F2495			0.010000
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	1F2495			0.010000
15031AA	BEANS-DRY-BLACK EYE PEAS(COWPEAS)	1F2495			0.010000
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	1F2495			0.010000
24001AA	BARLEY	1E2563			0.010000
24002EA	CORN, GRAIN-ENDOSPERM	1F2521			0.010000
24002HA	CORN, GRAIN-BRAN	1F2521			0.010000
24002SA	CORN SUGAR	1F2521			0.010000
24003AA	OATS	1E2563			0.010000
24004AA	RICE-ROUGH	1E2563			0.010000
24004AB	RICE-MILLED	1E2563			0.010000
24005AA	RYE-ROUGH	1E2563			0.010000
24005GA	RYE-GERM	1E2563			0.010000
24005WA	RYE-FLOUR	1E2563			0.010000
24006AA	SORGHUM (INCLUDING MILO)	8F2098			0.010000

CHEMICAL INFORMATION FOR CASWELL NUMBER 1238X

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Benoxycor Caswell #1238X CAS No. 98730-04-2 A.I. CODE: CFR No. 180.460	90d feeding- dog NOEL= 5.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:	90-Day rat study - NOEL=5 mg/kg-day. NOELs taken form FR notice.	UF -->1000 OPP Rfd= 0.004000 EPA Rfd= 0.000000	AD HOC Rfd/PR COMMITTEE 12/10/96	PROVISIONAL Rfd 12/10/96

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
24007AA	WHEAT-ROUGH	1E2563			0.010000
24007GA	WHEAT-GERM	1E2563			0.010000
24007HA	WHEAT-BRAN	1E2563			0.010000
24007WA	WHEAT-FLOUR	1E2563			0.010000
24012AA	MILLET	1E2563			0.010000
26001AA	BUCKWHEAT	1E2563			0.010000
26011AA	GUAR BEANS	1F2495			0.010000
270020A	CORN, GRAIN-OIL	1F2521			0.010000
270030A	COTTONSEED-OIL	1F2506			0.010000
27003WA	COTTONSEED-MEAL	1F2506			0.010000
270070A	PEANUTS-OIL	2F2720			0.010000
27008AA	SAFFLOWER-SEED	2F2601			0.010000
270080A	SAFFLOWER-OIL	2F2601			0.010000
270100A	SOYBEANS-OIL	2F2720			0.010000
28023AA	SOYBEANS-UNSPECIFIED	2F2720			0.010000
28023AB	SOYBEANS-MATURE, SEEDS DRY	2F2720			0.010000
28023WA	SOYBEANS-FLOUR, FULL FAT	2F2720			0.010000
28023WB	SOYBEANS-FLOUR, LOW FAT	2F2720			0.010000
28023WC	SOYBEANS-FLOUR, DEFATTED	2F2720			0.010000
50000DB	MILK-NON-FAT SOLIDS	5F1606			0.010000
50000FA	MILK-FAT SOLIDS	5F1606			0.010000
50000SA	MILK SUGAR (LACTOSE)	5F1606			0.010000
53001BA	BEEF-MEAT BYPRODUCTS	5F1606			0.010000
53001BB	BEEF(ORGAN MEATS)-OTHER	5F1606			0.010000
53001DA	BEEF-DRIED	5F1606			0.010000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	5F1606			0.010000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	2F2720			0.010000
53001LA	BEEF(ORGAN MEATS)-LIVER	2F2720			0.010000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	5F1606			0.010000
53002BA	GOAT-MEAT BYPRODUCTS	5F1606			0.010000
53002BB	GOAT(ORGAN MEATS)-OTHER	5F1606			0.010000
53002FA	GOAT(BONELESS)-FAT	5F1606			0.010000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	2F2720			0.010000
53002LA	GOAT(ORGAN MEATS)-LIVER	2F2720			0.010000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	5F1606			0.010000
53003AA	HORSE	5F1606			0.010000
53005BA	SHEEP-MEAT BYPRODUCTS	5F1606			0.010000
53005BB	SHEEP(ORGAN MEATS)-OTHER	5F1606			0.010000
53005FA	SHEEP(BONELESS)-FAT	5F1606			0.010000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	2F2720			0.010000

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CHEMICAL INFORMATION FOR CASWELL NUMBER 123BX

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FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
53005LA	SHEEP(ORGAN MEATS)-LIVER	2F2720			0.010000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	5F1606			0.010000
53006BA	PORK-MEAT, BYPRODUCTS	5F1606			0.010000
53006BB	PORK(ORGAN MEATS)-OTHER	5F1606			0.010000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	5F1606			0.010000
53006KA	PORK(ORGAN MEATS)-KIDNEY	2F2720			0.010000
53006LA	PORK(ORGAN MEATS)-LIVER	2F2720			0.010000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	5F1606			0.010000
55008BA	TURKEY-BYPRODUCTS	5F1606			0.010000
55008LA	TURKEY-GIBLETS (LIVER)	2F2720			0.010000
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	5F1606			0.010000
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	5F1606			0.010000
55008MC	TURKEY-UNSPECIFIED	5F1606			0.010000
55013BA	POULTRY,OTHER-BYPRODUCTS	5F1606			0.010000
55013LA	POULTRY,OTHER-GIBLETS(LIVER)	2F2720			0.010000
55013MA	POULTRY,OTHER-FLESH (+SKIN,W/O BONES)	5F1606			0.010000
55014AA	EGGS-WHOLE	5F1606			0.010000
55014AB	EGGS-WHITE ONLY	5F1606			0.010000
55014AC	EGGS-YOLK ONLY	5F1606			0.010000
55015BA	CHICKEN-BYPRODUCTS	5F1606			0.010000
55015LA	CHICKEN-GIBLETS(LIVER)	2F2720			0.010000
55015MA	CHICKEN-FLESH(W/O SKIN,W/O BONES)	5F1606			0.010000
55015MB	CHICKEN-FLESH(+SKIN,W/O BONES)	5F1606			0.010000

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Benoxycor Caswell #1238X CAS No. 98730-04-2 A.I. CODE: CFR No. 180.460	90d feeding- dog NOEL= 5.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:	90-Day rat study - NOEL=5 mg/kg-day. NOELs taken form FR notice.	UF -->1000 OPP Rfd= 0.004000 EPA Rfd= 0.000000	AD HOC Rfd/PR COMMITTEE 12/10/96	PROVISIONAL Rfd 12/10/96

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**			ARC	%RFD
U.S. POPULATION - 48 STATES	0.000191	0.000191	4.764250	0.000000		
U.S. POPULATION - SPRING SEASON	0.000181	0.000181	4.522275	0.000000		
U.S. POPULATION - SUMMER SEASON	0.000190	0.000190	4.762450	0.000000		
U.S. POPULATION - FALL SEASON	0.000196	0.000196	4.896600	0.000000		
U.S. POPULATION - WINTER SEASON	0.000194	0.000194	4.845675	0.000000		
NORTHEAST REGION	0.000192	0.000192	4.812050	0.000000		
NORTH CENTRAL REGION	0.000195	0.000195	4.871650	0.000000		
SOUTHERN REGION	0.000177	0.000177	4.431600	0.000000		
WESTERN REGION	0.000203	0.000203	5.076550	0.000000		
HISPANICS	0.000235	0.000235	5.866300	0.000000		
NON-HISPANIC WHITES	0.000188	0.000188	4.704650	0.000000		
NON-HISPANIC BLACKS	0.000180	0.000180	4.505575	0.000000		
NON-HISPANIC OTHERS	0.000212	0.000212	5.292850	0.000000		
NURSING INFANTS (< 1 YEAR OLD)	0.000210	0.000210	5.261475	0.000000		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000818	0.000818	20.450550	0.000000		
FEMALES (13+ YEARS, PREGNANT)	0.000135	0.000135	3.366875	0.000000		
FEMALES 13+ YEARS, NURSING	0.000167	0.000167	4.170375	0.000000		
CHILDREN (1-6 YEARS OLD)	0.000482	0.000482	12.042450	0.000000		
CHILDREN (7-12 YEARS OLD)	0.000312	0.000312	7.811600	0.000000		
MALES (13-19 YEARS OLD)	0.000205	0.000205	5.135525	0.000000		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000160	0.000160	4.008625	0.000000		
MALES (20 YEARS AND OLDER)	0.000128	0.000128	3.194775	0.000000		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000111	0.000111	2.763750	0.000000		

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.

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Attachment:

Final Review
11/19/96
Page 1 of 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Benoxacor CFR 180.460

CODEX NO. _____

CODEX STATUS:

☒ No Codex Proposal
Step 6 or Above

Residue (if Step 8): _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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PROPOSED U.S. TOLERANCES:

Petition No. 7E 3489

DEB Reviewer Cutchin

Residue: parent

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
All RACs with Metolachlor Tolerances	0.01

CANADIAN LIMITS:

☒ No Canadian Limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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MEXICAN LIMITS:

☐ No Mexican Limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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NOTES

Form Revised 1989

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File Update

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 02/24/97 BS

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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**New TMRC includes new, pending, and published tolerances.

DEPARTMENT OF TRANSPORTATION
40 CFR Part 180

[OPP-300449; FRL-5583-4]
RIN 2070-AB78

Benoxacor; Time-Limited Tolerances for Residues

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine (benoxacor) when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. This regulation is being issued in response to a petition for the establishment of a tolerance for residues of benoxacor requested by Ciba-Geigy Corp.

EFFECTIVE DATE: This regulation becomes effective February 14, 1997 and expires on February 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300449], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300449], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of

Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent enactment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence the RFA is inapplicable.

Under 5 U.S.C. 801(a)(1)(A), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(a).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 14, 1997.

Peter Caulkins,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By revising Sec. 180.460 to read as follows:

Sec. 180.460 Benoxacor; tolerances for residues.

Tolerances are established for residues of the inert ingredient (safener) benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine) when used in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. These tolerances expire on February 14, 1998.

[FR Doc. 97-4495 Filed 2-20-97; 8:45 am]

BILLING CODE 6560-50-F